K033654

JAN 1 5 2004

SECTION VI

510(k) Summary

Substantial Equivalence

In accordance with the requirements of 21 CFR § 807, this summary is formatted with the Agency's final rule ".... 510(k) Summaries and 510(k) Statements..." and can be used to provide equivalence summary to anyone requesting it from the Agency.

Manufacturer Teleflex Medical
600 Airport Road
Fall River, MA 02720-4740

Contact Person Lynn Matos
Phone: (508) 677-6582
Fax: (508) 677-6663
E-mail: lmatos@teleflexmedical.com

Date Prepared November 20, 2003

Device Information

Trade Name: Force Fiber™ Polyethylene Nonabsorbable Surgical Suture.

Common Name: Polyethylene Nonabsorbable Surgical Sutures.

Classification Name: Nonabsorbable Poly(ethylene terephthalate) Surgical Sutures

Indications for Use

Force Fiber™ Polyethylene Nonabsorbable Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Device Description

Force Fiber Nonabsorbable Surgical Suture meets all USP requirements for size 2-0. All other sizes meet USP requirements except for oversized diameter. Force Fiber Nonabsorbable Suture is available in size 2-0 through 2 (metric size 3 through 5) and is provided as undyed (white). The suture is a braided multifilament, is provided in a variety of lengths, with or without needles, with or without pledgets, and may be supplied in a variety of cut lengths or on ligating reels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2004

Ms. Lynn Matos
Regulatory Affairs Coordinator
Teleflex Medical
600 Airport Road
Fall River, Massachusetts 02720

Re: K033654
Trade/Device Name: Force Fiber™ Polyethylene Nonabsorbable Surgical Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable suture
Regulatory Class: II
Product Code: GAT
Dated: November 10, 2003
Received: November 21, 2003

Dear Ms. Matos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033654

510(k) Number (if known)

Device Name

Force Fiber™ Polyethylene Nonabsorbable Surgical Suture

Indications for Use

Force Fiber™ Polyethylene Nonabsorbable Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K033654